

REMARKS

This Amendment is submitted in reply to the Non-Final Office Action mailed on July 10, 2009. A Petition for a three month extension of time is submitted herewith this Amendment. The Commissioner is hereby authorized to charge \$1,110.00 for the Petition for a three month extension of time and any additional fees that may be required or credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3712036-00444 on the account statement.

Claims 1-32 are pending in the application. Claims 2, 4, 5, 12-25 and 28-32 were previously withdrawn from consideration. In the Office Action, Claims 1, 3, 6-11 and 27 are rejected under 35 U.S.C. §103(a). In response, Claims 1 and 6 have been amended. The amendments do not add new matter and are supported in the Preliminary Amendment at, for example, page 7, lines 5-14; page 8, line 17-page 9, line 11. In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claims 1, 3 and 27 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,766,330 to Knights et al. ("*Knights*"). Claims 6-11 and 26 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,221,418 to Bergenfield et al. ("*Bergenfield*"). In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully submit that the cited references are deficient with respect to the present claims.

Independent Claims 1 and 6 recite, in part, calcium absorption enhancers comprising calcium, at least one isoflavone and egg white, wherein the ratio of egg white/calcium is between 20 to 60 by weight. The amendments do not add new matter. The amendments are supported in the Preliminary Amendment at, for example, page 7, lines 5-14; page 8, line 17-page 9, line 11. Applicants have found that giving calcium and/or isoflavones in parallel with egg white considerably enhances calcium absorption. See, Preliminary Amendment, page 8, lines 10-16. Indeed, Applicants have surprisingly found that by giving egg white together with calcium, the absorption of calcium was significantly enhanced. Although not wishing to be bound by theory, Applicants believe that the phenomenon may be due to egg whites and isoflavones stabilizing the emulsion of calcium, preventing it from precipitating, or egg whites transformed into peptides

during digestion, and these peptides help to keep calcium soluble in the intestine. See, Preliminary Amendment, page 8, lines 10-16.

Further, isoflavones (e.g., soy isoflavones) are weak estrogens. They are 1000 fold less potent than natural estrogen. However, in women consuming a soy diet, circulating plasma levels of isoflavones are 1000 fold higher than estradiol and result in physiological effects. By analogy with estrogen, it is postulated that soy isoflavones, which bind to estrogen receptors (ERs), though with a higher affinity for ER β than ER α , may modulate gastrointestinal absorption and renal tubular reabsorption of calcium. See, Preliminary Amendment, page 7, lines 5-14; page 8, line 17-page 9, line 11. In contrast, Applicants respectfully submit that *Knights* and *Bergenfield* fail to disclose each and every element of the present claims.

Knights fails to disclose or suggest calcium absorption enhancers comprising calcium, at least one isoflavone and egg white, wherein the ratio of egg white/calcium is between 20 to 60 by weight as is required, in part, by the present claims. *Knights* does not even relate to calcium absorption enhancement. Instead, *Knights* is entirely directed toward avoiding calcium sedimentation if the disclosed power is dissolved in water. This is achieved by blending an insoluble calcium salt with a protein source. The resulting dry powder will form, after reconstitution in water, a suspension with no calcium sedimentation. See, *Knights*, Abstract. A suspension is a heterogeneous fluid containing solid particles. In other words, the calcium of *Knights* is still insoluble in the compositions. Since it is never dissolved, the calcium of *Knights* is not available for absorption and the composition in *Knights* is cannot be a calcium absorption enhancer. Indeed, the insoluble calcium of *Knights* appears to be somewhat masked by the protein used to avoid precipitation. See, *Knights*, Abstract.

The Patent Office asserts that “*Knights* et al disclose calcium absorption enhancer composition comprising . . . ratio egg white/calcium, 25 to 34.” See, Office Action, page 3, lines 3-7. However, the ratio of calcium to protein cited by the Patent Office at column 9, lines 22-25, does not even specify that the protein is egg white and the ratio does not even fall within the presently claimed ratio of 20 to 60. Instead, the ratio of 25% egg white to 34% calcium cited by the Patent Office is equal to 0.735, which is far outside the claimed ratios between 20 and 60. Accordingly, it is certainly not obvious to modulate a protein/calcium ratio of 0.735 to arrive at a

protein/calcium ratio in the range of 20-60. This is especially true wherein the present disclosure and *Knights* are directed to two entirely distinct goals.

Further, with respect to dependent Claim 3, the Patent Office asserts that “*Knights* is silent on egg whites containing ovalbumin, ovotransferrin and ovomucoid, however it is inherent that ovalbumin, ovotransferrin and ovomucoid are naturally occurring proteins in egg whites.” See, Office Action, page 3, lines 19-21. However, egg whites are a protein source useful in the present disclosure because it contains ovalbumin, ovotransferrin and ovomucoid in sufficient amounts. Indeed, other proteins do not have the same properties and, therefore, cannot be used for the purposes of the present disclosure. The use of ovalbumin, ovotransferrin and ovomucoid is not obvious in view of *Knights*, therefore, because any protein source will work for the composition of *Knights*, whereas the present disclosure specifically requires sufficient amounts of ovalbumin, ovotransferrin and/or ovomucoid.

Further, to satisfy the test for inherency, the Patent Office would be required to show that *Knights* necessarily (i.e., always or automatically) provides the ovalbumin, ovotransferrin and ovomucoid of the compositions of the present claims. That condition simply is not met under the present circumstances. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. See, MPEP 2112. *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993). As such, *Knights* fails to disclose each and every element of the present claims.

Bergenfield also fails to disclose or suggest that calcium absorption enhancers comprising calcium, at least one isoflavone and egg white, wherein the ratio of egg white/calcium is between 20 to 60 by weight as is required, in part, by the present claims. Instead, *Bergenfield* is entirely directed toward providing a baked product having a high protein content, and does not disclose a calcium absorption enhancer. See, *Bergenfield*, Abstract. At no place in the disclosure does *Bergenfield* disclose or even suggest that calcium absorption enhancers may include calcium, at least one isoflavone and egg white, wherein the ratio of egg white/calcium is between 20 to 60 by weight. As such, *Bergenfield* fails to disclose each and every element of the present claims.


The Patent Office asserts that *Bergenfield* discloses “egg whites in an amount by wt. of 28% to 32% and calcium caseinate in the amount by wt. of 39% to 42%.” See, Office Action, page 4, lines 6-7. Caseinates typically have a molecular weight in the range of 24 kDa. Calcium

has a molecular weight of 40 kDa. Therefore, the protein composition of *Bergenfield* contains about 0.065% weight% Ca. The weight ratio egg white/calcium is, therefore, about 460, which is well outside the presently claimed range of between 20 to 60 by weight. Additionally, the egg whites of *Bergenfield* are merely mentioned as one of a long laundry list of protein sources. However the specific egg white proteins of the present disclosure are not mentioned, nor is the importance of the use of same.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

K&L GATES LLP

BY 
Robert M. Barrett
Reg. No. 30,142
Customer No. 29157
Phone No. 312-807-4204

Dated: January 11, 2010